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example, relative to a composition which includes only 50% as much castor oil) breaking down or resolving the emulsion in the eye, for example, as measured by split-lamp techniques to monitor the composition in the eye for phase separation. Such rapid break down of the emulsion in the eye reduces vision distortion as the result of the presence of the emulsion in the eye, as well as facilitating the therapeutic effectiveness of the composition in treating dry eye disease.

Using reduced amounts of cyclosporin A, as in Composition II, to achieve therapeutic effectiveness mitigates even further against undesirable side effects and potential drug interactions. Prescribing physicians can provide (prescribe) Composition II to more patients and/or with fewer restrictions and/or with reduced risk of the occurrence of adverse events, e.g., side effects, drug interactions and the like, relative to providing Composition I.

While this invention has been described with respect to various specific examples and embodiments, it is to be understood that the invention is not limited thereto and that it can be variously practiced within the scope of the following claims.

What is claimed is:

1. A method of treating dry eye disease, the method comprising topically administering to the eye of a human in need thereof an emulsion at a frequency of twice a day, wherein the emulsion comprises cyclosporin A in an amount of about 0.05% by weight, polysorbate 80, acrylate/C10-30 alkyl acrylate cross-polymer, water, and castor oil in an amount of about 1.25% by weight; and

wherein the topical ophthalmic emulsion is effective in treating dry eye disease.

2. The method of claim 1, wherein the emulsion further comprises a tonicity agent or a demulcent component.

3. The method of claim 2, wherein the tonicity agent or the demulcent component is glycerine.

4. The method of claim 1, wherein the emulsion further comprises a buffer.

5. The method of claim 4, wherein the buffer is sodium hydroxide.

6. The method of claim 1, wherein the topical ophthalmic emulsion further comprises glycerine and a buffer.

7. The method of claim 1, wherein the emulsion comprises polysorbate 80 in an amount of about 1.0% by weight.

8. The method of claim 1, wherein the emulsion comprises acrylate/C10-30 alkyl acrylate cross-polymer in an amount of about 0.05% by weight.

9. The method of claim 1, wherein the emulsion further comprises glycerine in an amount of about 2.2% by weight and a buffer.

10. The method of claim 9, wherein the buffer is sodium hydroxide.

11. The method of claim 1, wherein, when the emulsion is administered to an eye of a human, the blood of the human has substantially no detectable concentration of cyclosporin A.

12. The method of claim 6, wherein the emulsion has a pH in the range of about 7.2 to about 7.6.

13. The method of claim 1, wherein the emulsion is as substantially therapeutically effective as a second emulsion administered to a human in need thereof at a frequency of twice a day, the second emulsion comprising cyclosporin A in an amount of 0.1% by weight and castor oil in an amount of 1.25% by weight.

14. The method of claim 1, wherein the emulsion achieves at least as much therapeutic effectiveness as a second emul-

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sion administered to a human in need thereof a frequency of twice a day, the second emulsion comprising cyclosporin A in an amount of 0.1% by weight and castor oil in an amount of 1.25% by weight.

15. The method of claim 1, wherein the emulsion breaks down more quickly in the eye of a human, once administered to the eye of the human, thereby reducing vision distortion in the eye of the human as compared to a second emulsion that contains only 50% as much castor oil.

16. The method of claim 1, wherein the emulsion, when administered to the eye of a human, demonstrates a reduction in adverse events in the human, relative to a second emulsion administered to a human in need thereof a frequency of twice a day, the second emulsion comprising cyclosporin A in an amount of 0.1% by weight and castor oil in an amount of 1.25% by weight.

17. The method of claim 16, wherein the adverse events are side effects.

18. A method of reducing side effects in a human being treated for dry eye syndrome, the method comprising the step of topically administering to the eye of the human in need thereof an emulsion at a frequency of twice a day, wherein the emulsion comprises:

cyclosporin A in an amount of about 0.05% by weight; castor oil in an amount of about 1.25% by weight; polysorbate 80 in an amount of about 1.0% by weight; acrylate/C10-30 alkyl acrylate cross-polymer in an amount of about 0.05% by weight;

a tonicity component or a demulcent component in an amount of about 2.2% by weight;

a buffer; and

water;

wherein the topical ophthalmic emulsion has a pH in the range of about 7.2 to about 7.6.

19. The method of claim 18, wherein the buffer is sodium hydroxide.

20. The method of claim 18, wherein the tonicity component or the demulcent component is glycerine.

21. The method of claim 18, wherein, when the emulsion is administered to the eye of a human for treating dry eye syndrome, the blood of the human has substantially no detectable concentration of the cyclosporin A.

22. The method of claim 18, wherein the emulsion is effective in treating dry eye disease.

23. A method of treating dry eye disease, the method comprising the step of topically administering to an eye of a human in need thereof an emulsion at a frequency of twice a day, the emulsion comprising:

cyclosporin A in an amount of about 0.05% by weight; castor oil in an amount of about 1.25% by weight; polysorbate 80 in an amount of about 1.0% by weight; acrylate/C10-30 alkyl acrylate cross-polymer in an amount of about 0.05% by weight;

glycerine in an amount of about 2.2% by weight;

sodium hydroxide; and

water;

wherein the emulsion is effective in treating dry eye disease.

24. The method of claim 23, wherein the emulsion has a pH in the range of about 7.2 to about 7.6.

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